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PRM 20-26
(70FR34699)

September 19, 2006

Michael T. Lesar
Chief, Rules and Directives Branch
U.S. Nuclear Regulatory Commission,
Washington, DC 20555–0001

Dear Mr. Lesar:

Subject: Petition for Rulemaking dated May 6, 2005, filed by James Salsman
Docket No. PRM–20–26

Kennecott Uranium Company is the operator of the last remaining conventional uranium mill in Wyoming, which is located in the Great Divide Basin in Sweetwater County, Wyoming and licensed under Source material License Number: SUA-1350. Kennecott Uranium Company submitted comments dated August 22, 2005 on the original petition.

The above referenced petition for rulemaking filed by James Salsman is of concern to Kennecott Uranium Company since it directly addresses the regulatory limits for uranium exposure. Kennecott Uranium Company again requests that the petition be denied.

Mr. Salsman wrote to you on Sunday July 23, 2006 via e-mail. The subject heading of his message (found at http://ruleforum.llnl.gov/cgi-bin/downloader/PRM_2026_public/1564-0015.pdf) relates to a request for a status update and a notification of change of address however, within the text of his letter, he indicates that he wants to significantly broaden the scope of his earlier proposal PRM 20-26 to include consideration of depleted uranium neurotoxicity. In this context, he submits references to 4 papers, and says the following:

> *I am considering submitting another petition very similar to PRM-20-26 asking that this neurotoxicity information also be used to set exposure limits.*
>
> *Instead of doing that, can the above citations be informally transmitted to the PRM-20-26 decision-makers, since the subject and necessary action are so similar? I don't want to formally amend the petition, since I know that might result in a re-opened comment period and further delays, but I am very interested in asking that the people who are already looking at previously unconsidered uranium toxicities to also consider neurotoxicity.*
>
> *Is there a way to do that informally? Can I just ask that you forward this as if it were a late public comment? If so, please do.*

Mr. Salsman's position is worrisome in that he seeks to substantially broaden the scope of the petition while suggesting that he would like private access with information to the committee, without allowing an opportunity for public review and comment. This approach is not in the public's best interest. Kennecott Uranium Company believes that any broadening of the scope of the petition to include any additional information should involve reopening the petition for rulemaking to public comment.

On August 31, 2006, Ms. Katie Sweeney Associate General Counsel of the National Mining Association (NMA) contacted you in this regard and was informed that the additional issue of neurotoxicity would be considered by the Commission without reopening the petition to public comment. Kennecott Uranium Company vehemently disagrees with this decision. However, since James Salsman was permitted to broaden the scope of his petition for rulemaking after the public comment period expired on August 29, 2005, Kennecott Uranium Company is submitting the following comments on the issue of neurotoxicity raised by James Salsman and the papers referenced in his e-mail dated Sunday July 23, 2006:

Template = SECY-067

SECY-02

Effects of short-term and long-term depleted uranium exposure on open-field behavior and brain lipid oxidation in rats Wayne Briner, Jennifer Murray

Nuclear Regulatory Commission (NRC) regulations, specifically 10 CFR Part 20.1201(e) states:

> *(e) In addition to the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity (see footnote 3 of appendix B to part 20).*

This paper describes dosing rats with the human equivalent of 54 grams in 6 months of depleted uranium. This dose is over two (2) orders of magnitude in excess of current regulatory limits. Exposures of this magnitude are already addressed by existing regulation thus this paper has no bearing on exposures at or below current regulatory limits.

Bioaccumulation and behavioural effects of depleted uranium in rats exposed to repeated inhalations Marjorie Monleau, Cyrill Bussy, Philippe Lestaevel, Pascale Houpert, Francois Paquet, Valerie Chazel

This paper discusses equivalent doses of twenty-four (24) milligrams per three-(3) week period given via inhalation as four (4) doses per week. This would equate to a human equivalent dose of eight (8) milligrams per week, which is near the 10 CFR 20.1201(e) chemical dose limit of ten (10) milligrams per week. However, it also should be noted that 10 CFR Part 20.1101(b) states:

> *(b) The licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).*

Thus any dose limit in the regulations is an absolute maximum dose and any doses to workers or to the general public must, in addition to the actual dose limit, be constrained by ALARA as well. Thus the actual doses received by workers are in most cases a fraction of the maximum dose allowed by regulation and do not reach the doses discussed in this paper. Thus, while an eight (8) milligram per week dose may approach the maximum dose allowed by regulation it is far in excess of actual doses received by workers given the application of the ALARA principle. It is also far in excess of the maximum allowable dose to members of the general public of 3E-12 microcuries per milliliter (Day), 9E-13 microcuries per milliliter (Week) or 9E-14 microcuries per milliliter(Year) depending upon the chemical retention time of the radionuclide (Day, Week or Year)

In addition, in Appendix 1 Dr. Standler states, *"This information looks premature to influence public policy with respect to the issues the NRC is considering."*

The brain is a target organ after acute exposure to depleted uranium P. Lestaevel, P. Houpert, C. Bussy, B. Dhieux, P. Gourmelon, F. Paquet.

This paper examines a human equivalent dose of ten (10) milligrams per week administered to rats via a single intraperitoneal injection. This dose administration method does not reproduce normal doses to workers via inhalation since the doses received by workers are generally spread over an entire workweek and not received as a single instantaneous dose. In addition, the paper is looking at a human equivalent uranium dose at the regulatory limit of ten (10) milligrams per week which, as stated previously, is not realistic for most workers since in addition to the mandated dose limit in the regulations, doses must also be maintained as low as reasonably achievable (ALARA) as per 10 CFR Part 20.1201(e).

The paper also states that the rats suffered from altered sleeping and feeding patterns and trace uranium in the brain at 3 days. The problem with this result is that the ten (10) milligram dose limit is a weekly dose limit so that if in a rare event a worker received the maximum ten (10) milligram dose it would be received over a four (4) or five (5) day period and the uranium received on day one would be clearing by day three before the entire ten (10) milligram dose had been received.

In addition, regarding the paper, Dr. Standler states (in Appendix 1), *"This may have implications for trying to get uranium shrapnel out of people's bodies quickly, but may not have implications for the issues that the NRC regulates."*

Jiang, G. C. and M. Ashner (2006) Neurotoxicity of depleted uranium: reasons for increased concern," Biological Trace Element Research 110: 1-18 PMID 16679544.

This paper is a review of existing literature referencing many other papers (ninety-two (92) references are cited in the bibliography) including the above discussed one by Wayne Briner and Jennifer Murray. It presents no new experimental data.

In addition to these comments, in Appendix 1 is a letter prepared by Dr. Standler in which she reviews the four-(4) papers referenced by James Salsman in his e-mail dated Sunday July 23, 2006.

Conclusions:

1. Kennecott Uranium Company disagrees with allowing the petitioner, James Salsman, to broaden the scope of his petition for rulemaking to include the neurotoxicity of uranium via an e-mail submitted after the August 29, 2005 deadline for comment has expired, without reopening the public comment period.
2. Since the petitioner was permitted to broaden the scope of his petition to include neurotoxicity Kennecott Uranium Company is submitting these comments on the papers referenced by him in his e-mail dated Sunday July 23, 2006.
3. Kennecott Uranium Company believes that the paper entitled *Effects of short-term and long-term depleted uranium exposure on open-field behavior and brain lipid oxidation in rats* does not apply since the doses described in the paper far exceed the maximum allowable ten (10) milligram per week dose specified in 10 CFR Part 20.1201(e). The doses described in this paper are already addressed by existing regulations.
4. The paper entitled *Neurotoxicity of depleted uranium: reasons for increased concern* is a literature review and presents no new experimental data.
5. The paper entitled "*The brain is a target organ after acute exposure to depleted uranium*" examines a human equivalent dose of ten (10) milligrams per week administered to rats via a single intraperitoneal injection, which is not equivalent to a dose received by workers via inhalation since it is received instantaneously. In addition, human equivalent doses as high as the regulatory limit do not mimic doses to workers in that in addition to meeting the regulatory dose limit doses to workers must also be as low as reasonably achievable meaning that de facto doses are generally well below regulatory limits. Also, regarding the paper, Dr. Standler states, *"This may have implications for trying to get uranium shrapnel out of people's bodies quickly, but may not have implications for the issues that the NRC regulates."*
6. The paper entitled *Bioaccumulation and behavioural effects of depleted uranium in rats exposed to repeated inhalations* again examines a human equivalent dose (approximately eight (8) milligrams per week) which is higher than actual doses to workers when the requirements to maintain doses as low as reasonably achievable (ALARA) as stipulated by 10 CFR Part 20.1101(b) are followed. Also, Dr. Standler states, *"This information looks premature to influence public policy with respect to the issues the NRC is considering."*
7. Kennecott Uranium Company requests that the petition be denied.

Kennecott Uranium Company appreciates the opportunity to comment on these issues. If you have any questions please do not hesitate to contact me.

Sincerely yours,

Oscar Paulson
Facility Supervisor

cc: Marty Stearns – Rio Tinto Energy America (RTEA)
Katie Sweeney – National Mining Association (NMA)

Appendix 1

September 5, 2006

Nancy Standler MD, Ph.D.
P.O. Box 2205
Cedar City Utah 84721

Michael T. Lesar
Chief, Rules and Directives Branch
U.S. Nuclear Regulatory Commission
Washington, DC 20555–0001

Dear Mr. Lesar:

Subject: **Petition for Rulemaking dated May 6, 2005, filed by James Salsman Docket No. PRM–20–26**

My name is Dr. Nancy Standler MD, Ph.D. and I am a working board certified pathologist with both an MD degree from University of Pittsburgh and PHD in Biophysics and Radiation Biology from the University of Rochester. I previously submitted comments concerning Mr. Salsman's original petition for rulemaking. I have reviewed the four- (4) papers cited by Mr. Salsman in his July 23, 2006 via e-mail. The following are my conclusions:

1. **Effects of short-term and long-term depleted uranium exposure on open-field behavior and brain lipid oxidation in rats Wayne Briner, Jennifer Murray**

The protocol involves supplying drinking water to rats containing very large uranium doses for two weeks and six-month time periods. Equivalent human adult doses assuming 2 L of contaminated water consumption daily are 150 mg/L * 2 L/day * 14 days = 4.2 grams in two weeks and 150 mg/dL * 2 L/day * 180 days = 54 grams in 6 months. Nuclear Regulatory Commission (NRC) regulations, specifically 10 CFR Part 20.1201(e) state:

> *(e) In addition to the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity (see footnote 3 of appendix B to part 20).*

There is already a 10-milligram per week soluble uranium intake limit. This equates to a 0.5 gram per year dose limit assuming that the individual is on vacation for 2 weeks each year and works 50 weeks each year. 54 grams in 6 months is over 2 orders of magnitude above the existing dose limit. Thus, the national uranium standards already cover the problem, as there is no reason to suppose that the chemical toxicity of depleted uranium acetate is anything different from the chemical toxicity of natural uranium acetate. Thus, the issue is just addressed with existing standards and there is no need to go further.

2. **Bioaccumulation and behavioural effects of depleted uranium in rats exposed to repeated inhalations Marjorie Monleau, Cyrill Bussy, Philippe Lestaevel, Pascale Houpert, Francois Paquet, Valerie Chazel**

The experimental protocol was to force rats to inhale UO2 aerosols for 30 minutes 4 times per week for 3 weeks, to produce a total lung take of 40 micrograms per gram of lung tissue. If you assume a typical human lung weight for both lungs taken together of 600 grams, this would be a

dose of 40 micrograms UO2 per gram lung tissue * 600 grams total lung tissue in humans = 24 milligrams UO2 given over three weeks. Inhalation exposure 4 times per week for 3 weeks simulates some forms of occupational exposure. 24 milligrams given over 3 weeks approximates the 10 milligram per week dose limit for soluble uranium in 10 CFR Part 20.1201(e). This dose was able to bump the concentrations of uranium in brain tissue the day following the last exposure up to around 580 ng U/g tissue in olfactory bulb (expected to be the highest because it is in the nose), 130 to 150 ng U/g tissue in cortex and hippocampus, and 40 ng U/g tissue in cerebellum. This uranium, despite being given over a 3 week period, cleared pretty rapidly, with near 100% clearance at 3 days from the olfactory bulb; 80% clearance at 3 days and near 100% clearance at 8 days from the cortex; 50% clearance at 3 days and near 100% clearance at 8 days from the hippocampus; and 50% clearance at 3 days and 80% clearance at 8 days from the cerebellum. There is no data available past 8 days after the end of the exposure. The authors also present some behavioral data that suggests fairly mild behavioral changes including possibly mild impairment of spatial working memory at 6 days post exposure, but this data is probably not as reliable as the chemical measurements, and, for example, exhibits in figure 3 what appears to be an aberrantly high control value for 6d post-exposure rats' spatial working memory, which leads to a statistical difference with the 6d post-exposure uranium group, although the 6d post-exposure uranium group appears to be nearly identical to the 2 day post exposure control group and the 2 day post exposure uranium group for this measurement. The other behavioral parameters measured that had statistically significant results included a few values in locomotor behavior and rearing behavior, but I don't know how much weight to give these very soft behavioral differences. In summary with respect to the NRC issues, it looks like there can be rapid (but with specific site variations) rate of clearance of uranium from brain in rats, that might or might not produce some (mild) behavioral differences out to 6 days, with no behavioral data being available farther out. This information looks premature to influence public policy with respect to the issues the NRC is considering.

3. **The brain is a target organ after acute exposure to depleted uranium P. Lestaevel, P. Houpert, C. Bussy, B. Dhieux, P. Gourmelon, F. Paquet.**

The model in this paper is intraperitoneal injection of depleted uranyl nitrate in rats at a single dose 144 micrograms per kilogram of rat for the initial study, and a follow-up dose related study at 70 micrograms per kilogram of rat. These numbers would be equivalent in people to 10 mg per 70 kg man and 5 mg per 70 kg man. These are obviously more reasonable doses than were used in the Briner paper, and the 10 milligrams per 70 kilogram man is equivalent to the 10 milligram weekly dose limit for soluble uranium in 10 CFR Part 20.1201(e) cited above. This is probably why the dose of 144 micrograms per kilogram of rat was selected for the study. The dose limit is a weekly one and it is assumed that the ten (10) milligrams would be ingested over a weeks work (probably over five (5) days) and not in a single (essentially instantaneous) intraperitoneal injection so the results of the experiment may not duplicate actual conditions. What the authors see is altered sleeping and feeding patterns and trace uranium in the brain at 3 days (but none in the kidneys, as it has cleared by day 3) in the rats given the higher dose, but no behavioral disturbances and no trace uranium in the brain by the third day in the lower doses. The paper is well done and probably "real." My guess is that the rats felt ill and didn't eat or sleep normally, but then were better once the uranium had cleared their nervous systems (which it was obviously able to do promptly, but not quite so promptly as the kidneys can clear their uranium load). This may have implications for trying to get uranium shrapnel out of people's bodies quickly, but may not have implications for the issues that the NRC regulates.

4. **Neurotoxicity of Depleted Uranium Reasons for Increased Concern George C.T. Jiang and Michael Aschner**

Jiang and Aschner's paper "*Neurotoxicity of Depleted Uranium*" is a review paper and does not introduce any new data. The majority of the work they cite is in rodents. The human literature cited pertains in large part to Gulf War veterans, and there is some suggestion that there is some neurotoxicity related to embedded shrapnel exposures. This may make a case that every attempt

should be made to remove depleted uranium shrapnel from people promptly, but it is unclear that additional regulations are needed, since embedded undepleted uranium in people would also not be a good idea, and appears to be clearly covered by existing NRC regulations at the doses in question.

Thank you for your concern with the uranium issues and for reviewing this letter. If you have any questions please do not hesitate to contact me.

Sincerely yours,

Nancy Standler, MD PhD

Nancy Standler MD, Ph.D.